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| 10/069,448      | 08/07/2002  | Lilian Fuchshuber    | 468452000200        | 1448             |

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EXAMINER

VENKAT, JYOTHSNA A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1615

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/069,448

Applicant(s)

FUCHSHUBER ET AL.

Examiner

JYOTHSNA A VENKAT

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).


\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/1/2004
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

 Receipt is acknowledged of amendment, and Ids filed on 4/1/04. Claims 12-17 have been added as per applicant's amendment dated 4/1/04. Claims 1-10 and 12-~~16~~<sup>7</sup> are pending in the application and the status of the application is as follows:

The following new grounds of rejection are necessitated by the amendment.

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 16-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is new matter rejection.**

3. There is no support in the specification at page 4 for mixtures of surfactants.

4. The support in claim 17 at page 6 is for the preferred embodiment, wherein the bulking agent in an amount from 2-5% and not greater than 50% w/w of the organic bulking agent.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4-6, 8, 10, 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by U. S. Patent 5,866, 152('152).
3. See col.2, line 22 for PEG 400. See the examples for polyoxyethylene lauryl sulfate. This species is within the genus of alkyl ether sulfate.
4. See col.2, lines 15-31 for polyethylene glycol (PEG), which reads on the claimed organic bulking agent. Since the bulking agent is same, claim 4 is inherent. See examples for claim 7. see col.2, lines 36-46 for claim 8. The specification does not define the meaning of "condition" and it is the examiners position that the patent, which discloses shampoo for the control of ectoparasites reads on the term "condition".

#### ***Response to Arguments***

5. Applicant's arguments filed 4/1/04 have been fully considered but they are not persuasive.
6. Applicants are notified that claim 7 is not anticipated in view of applicant's explanation with respect to the examples.
7. Applicants argue that all the examples teach aqueous compositions and the water present in the compositions is greater than the claimed "less than 20%" or "substantially non aqueous compositions".
8. In response to this, applicant's attention is drawn to col.2, lines 33-35. Adding the higher ranges yields the water content being less than 20% . Reference is valid for the entire disclosure and not to the examples only. In response to applicant's argument that the references fail to

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show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., water content) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore the patent anticipates the claims.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of U. S. Patent '152 and WO 87/04617('617) and U. S. Patent 6,207, 694('694).

12. **The patent '512 does not teach the limitation added for the new claims 12-16.**

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The patent '512 does not teach the limitations of claims 2-3 wherein the concentration of the bulking agent is greater than 20% or greater than 50% or the pharmaceutically active agent as antifungal agents of claims 9, 12 or the specific antifungal agent of claim 13 or the specific surfactant of claim 16. All the examples in the patent teach water content greater than 20 %. However the patent at col.2 suggests the water content less than 20%. This is obtained when one skilled in the art adds the higher values for active ingredient, anionic surfactant, and polyhydric alcohol. The WO document teaches the concentration of the bulking agent PEG as 40-80%. The WO document also teaches non- aqueous compositions. See the examples. The patent '694 teaches antidandruff compositions using the antifungal agent at the paragraph bridging cols. 2-3, and also the specific sodium laureth sulfate, specific antifungal agent of claim 13. The patent also teaches foam booster which is Betaine under example 1. With respect to claim 15 limitation optimizing the water content is within the ken of the skilled chemist.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare compositions of '152 and increase the concentration of the PEG of the patent to greater than 20% and combine with anti fungal agent for the control of dermal infection. The motivation to use higher concentration of PEG stems from the teaching of WO document that at higher concentration the PEG can dissolve the active ingredients so that better fungicidal properties are exhibited and the PEG also acts as penetration enhancer. This is a prima facie case of obviousness.

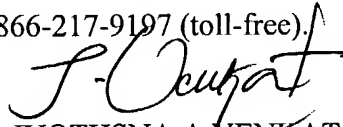
Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A VENKAT whose telephone number is 571-272-

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0607. The examiner can normally be reached on Monday-Thursday, 9:30-7:30:1st and 2nd Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THURMAN K PAGE can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
JYOTHSNA A VENKAT  
Primary Examiner  
Art Unit 1615

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